UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,201	08/22/2000	Gerardo V. Noriega	19635-000210US	1112

20350 7590 11/19/2002

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
NGUYEN, VI X	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/644,201	NORIEGA ET AL.	
	Examiner	Art Unit	
	Victor X Nguyen	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) *26,40-66 and 71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,27-39,67-70 and 72-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-25, 27-39, 67-70 and 72-74, 76-78 are rejected under 35 U.S.C. 102 (e) as being clearly anticipated by Ressemann et al (U.S. 5,897,567).

As to claim 1, Ressemann et al discloses in figs 1 and 12 an assembly having all the limitation as recited in the above listed claim, including: a guide wire (42); a drive shaft (26, 92), wherein said drive shaft (26, 92) including a distal tip (figs 1 and 12) can be rotated and created a path through stenotic material.

As to claims 2 and 5-8, Ressemann et al discloses in figs 1 and 12; wherein the guide wire (42) has a diameter between approximately 0.009 inches and 0.035 inches (col. 7, lines 29-32); wherein the assembly further including a detachable motor (24) coupled to the drive shaft (26, 92), wherein said proximal end of the drive shaft (26, 92) can be manually rotated; the distal

tip is flattened and twisted (col. 13, lines 4-14 and lines 59-64); and wherein the distal end of the hollow guide wire (42) is steerable.

As to claims 9-12, Ressemann et al discloses in figs 1 and 12; wherein a housing (36) coupled to the proximal end of the hollow guide wire (42); wherein said housing (36) including an actuator (52), wherein the drive shaft (26, 92) defines a longitudinal axis and the actuator (52) moves the drive shaft (26, 92) along the longitudinal axis; wherein the actuator (52) can extend the drive shaft (26, 92) up to 5 centimeters beyond the distal end of the hollow guide wire (42); and wherein the housing (36) includes an aspiration port (80, 82 , fig 2) coupled to the hollow guide wire (42).

As to claims 13-15, Ressemann et al discloses in figs 1 and 12; wherein the hollow guide wire (42) is in stationary position while the drive shaft (26, 92) is rotated, wherein said distal tip of the drive shaft is radio-opaque (col. 13, lines 45-67); and wherein the drive shaft (26, 92) facilitated transportation of a removed stenotic material.

As to claims 16-19, Ressemann et al discloses in figs 1 and 12; wherein a support system having a distal end, wherein the hollow guide wire (42) passes through the support system in order to allow the distal tip is positioned beyond the distal end of the hollow guide wire (42) and the support system; wherein the support system includes placing means disposed near distal end of the support system within the body lumen; and wherein the hollow guide wire (42) is through a vasculature and the drive shaft (26, 92) defines a longitudinal axis, wherein the distal tip is deflected off the longitudinal axis.

As to claim 20, Ressemann et al discloses in figs 1 and 12 an assembly having all the limitation as recited in the above listed claim, including: a hollow guide wire (42); a rotating

mechanism coupled to the drive shaft (26, 92); wherein an actuator (52) coupled to the drive shaft (26, 92); and wherein the activation of the actuator (52) advances the rotatable drive shaft (26, 92) from a retracted position to an extended position; wherein said drive shaft (26, 92) including a distal tip (figs 1 and 12) can be rotated and created a path through stenotic material.

As to claims 21-24, Ressemann et al discloses in figs 1 and 12, the distal tip is flattened and twisted (col. 13, lines 4-14 and lines 59-64), wherein said distal tip portion creates a path forward of the hollow guide wire (42); and wherein the distal tip portion includes a plurality of wires (102) connected at their ends.

As to claims 25, 27-30, Ressemann et al discloses in figs 1 and 12, wherein the hollow guide wire (42) is advanced through a body lumen without the need of a separate guide wire; wherein the rotating mechanism and actuator (52) are coupled together, wherein the rotating mechanism and actuator (52) are independently rotated and advanced; and wherein the rotating mechanism is removably attached to the drive shaft (26, 92); wherein the lumen of the hollow guide wire (42) aspirated fluids and debris from stenosis.

As to claim 31, Ressemann et al discloses in figs 1 and 12, wherein the system including an elongate member (figs 1 and 12); a drive shaft (26, 92) rotatably and translatably in the passage of the elongate member (figs 1 and 12); and wherein a flattened and twisted distal tip (col. 13, lines 4-14 and lines 59-64) attached to the drive shaft (26, 92), wherein the drive shaft (26, 92) and the distal tip are moveable between a retracted configuration and an extended configuration.

As to claims 32-34, Ressemann et al discloses in figs 1 and 12, wherein the distal tip (col. 13, lines 4-14 and lines 59-64) is in a retracted configuration, wherein said distal tip is sharpened and included at least two turns.

As to claims 35-37, Ressemann et al discloses in figs 1 and 12, wherein the elongate member (figs 1 and 12) is a hollow guide wire (42) and has a steerable tip; wherein the hollow guide wire (42) has a diameter between approximately 0.009 inches and 0.035 inches (col. 7, lines 29-32).

As to claims 38-39, Ressemann et al discloses in figs 1 and 12, the system further including a rotating mechanism coupled to the drive shaft (26, 92) and wherein the rotating mechanism is detachable from a proximal end of the drive shaft (26, 92).

As to claim 67, Ressemann et al discloses in figs 1 and 12 an assembly having all the limitation as recited in the above listed claim, including: a hollow guide wire (42); a rotatable drive shaft (26, 92) having a shaped distal tip, the rotatable wire received within the passage of the hollow guide wire (42); and wherein the rotating inner wire is within the guide wire (42) and advancing the drive shaft (26, 92) into the occlusive material; wherein a package contained the hollow guide wire (42), rotatable wire and the instructions for use.

As to claims 68-70 and 72, Ressemann et al discloses in figs 1 and 12; wherein the rotation of the distal tip creates at least as large as the outer diameter of the hollow guide wire (42), wherein said hollow guide wire (42) has a diameter between approximately 0.009 inches and 0.035 inches (col. 7, lines 29-32) and has a steerable distal portion.

As to claims 73-74 and 76-78, Ressemann et al discloses in figs 1 and 12, wherein the kit further including a support system is sized to received the hollow guide wire (42) and a guiding

catheter (14); wherein the kit further including a power supply and a motor (24) and an attachment mechanism for detachably coupling the motor (24) to the drive shaft (26, 92); wherein the power supply includes a sheath cover (40,58).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 75 and 79 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ressemann et al in view of Noriega (U.S. 6,059,767).

As to claim 75, Ressemann teaches all aspect of the claimed invention except including a second guide wire, wherein the support system is advanced through the body lumen over the second guidewire. Noriega teaches a second guide wire, wherein the support system is advanced through the body lumen over the second guidewire (col. 4, lines 45-67 and col. 5, lines 1-14) in order to improve the efficiency of the catheter and to provide a better positioned at a selected tissue site. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ressemann by adding a second guide wire, wherein the support system is advanced through the body lumen over the second guide wire in order to improve the efficiency of the catheter and to provide a better positioned at a selected tissue site.

As to claim 79, Ressemann teaches all aspect of the claimed invention except the housing is coupled to the hollow guide wire through a luer. Noriega teaches the housing is coupled to the hollow guide wire through a luer (see figs 2, 4 and 5) in order to facilitate fluids going through

the guide wire. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ressemann by adding the housing is coupled to the hollow guide wire through a luer in order to facilitate fluids going through the guide wire.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,662,671 to Barbut et al U.S. Pat. No. 6,179,851 to Barbut

U.S. Pat. No. 6,066,149 to Samson et al U.S. Pat. No. 5,116,350 to Stevens

U.S. Pat. No. 4,990,134 to Auth

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen
Examiner
Art Unit 3731

vn
November 11, 2002

KEVIN T. TRUONG
PRIMARY EXAMINER
11/18/02